

Notice of Allowability

Application No.

09/557,907

Examiner

Michael C. Wilson

Applicant(s)

HORTON ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the interview on 11-6-06.
2. ☒ The allowed claim(s) is/are 1,3-7,16-18,30-35,38-41,43,46-50,66,69,71-74,77,78 and 83-86.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20061111</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Elizabeth Haanes and Paul Calvo on 11-6-06.

The application has been amended as follows:

Claim 1 has been amended as follows:

A method of treating cancer or metastasis thereof in a mammal, comprising:

administering into a muscle of a mammal with cancer or metastasis thereof, a DNA plasmid comprising a polynucleotide which encodes interferon-alpha or an active fragment thereof, operably associated with a promoter;

wherein said muscle has not been treated with an agent that destroys muscle tissue;

wherein said DNA plasmid is administered free from ex vivo cells;

wherein said interferon alpha is expressed in vivo, and is present in the blood stream of said mammal in an amount effective to treat said cancer, or metastasis thereof.

Art Unit: 1632

Support for “muscle has not been treated with an agent that destroys muscle tissue” is found on pg 11, lines 1-10, which describes agents that destroy muscle tissue, including bupivacaine, barium chloride, sucrose, polyninyl pyrrolidine, intercalaters, histones, needless or needle-free injectors and surgical instruments. Accordingly, claim 1 excludes the agents in the paragraph on pg 11, lines 1-10.

The following is an examiner's statement of reasons for allowance:

The written description rejection regarding the phrase “administering into a non-injured muscle of a mammal” in claim 1 has been withdrawn in view of the amendment.

The rejection of claims 1, 3, 7, 35, 38 and 43 under 35 U.S.C. 102(a) as being anticipated by Lawson (J. Interferon and Cytokine Res., May 1997, Vol. 17, pg 255-261) has been withdrawn because IFN titers of ≤ 3.9 are considered “not detected.” “IFN titers were detected in groups of mice with regenerating muscle induced by crush injury but were not detected in groups of mice with either regenerating muscle induced by bupivacaine treatment or normal mature muscle (Table 4).” Accordingly, IFN titers of ≤ 3.9 cannot be “an amount sufficient to treat said cancer, or metastasis thereof” as claimed.

All of the 103 rejections are withdrawn because they are based on or rely upon Lawson (J. Interferon and Cytokine Res., May 1997, Vol. 17, pg 255-261).

The prior art made of record and not relied upon remains pertinent to applicant's disclosure:

Manthorpe cited in the withdrawn obviousness type double patenting rejection (US Patent 6,875,748; Application No: 09/839,574, filed 4-23-01 and having priority to 11-28-00) was not available as prior art at the time the invention claimed in the instant application was made. The claimed invention in the instant application was at least taught in parent application 09/196,313, filed 11-20-98 to which applicants claim priority (see for example pg 59). Therefore, Manthorpe (effective filing date = 11-28-00) was not available as prior art at the time the invention claimed in the instant application was made (effective filing date is at least 11-20-98).

Wolff (US Patent 6,228,844) claims a method for stimulating vascular growth in the heart of a vertebrate, comprising injecting into the myocardium of the vertebrate a noninfectious, nonintegrating DNA construct comprising a promoter operably linked to a DNA sequence encoding vascular endothelial growth factor; wherein said DNA construct is injected in an amount sufficient that uptake of said DNA construct into cardiac cells of the vertebrate occurs, and sufficient expression of said vascular endothelial growth factor results, to stimulate vascular growth; and wherein said DNA construct is free from association with transfection-facilitating proteins, viral particles, liposomal formulations, charged lipids, and calcium phosphate precipitating agents. '844 suggested delivering interferons using DNA and delivering DNA to treat cancer. '844 did not teach IFN- α or obtaining expression levels of a protein in the serum that were capable of treating cancer by administering the DNA intramuscularly or into the peritoneal cavity as currently claimed.

Wolff (US Patent 6,706,694; Application No: 09/588,655) claims a method for delivering a physiologically active polypeptide to a vertebrate heart, comprising: administering in vivo into heart muscle of a vertebrate a composition comprising a DNA operably encoding said physiologically active polypeptide through association with a promoter which directs synthesis of said polypeptide in vertebrate heart cells, and a pharmaceutically acceptable carrier; wherein said polynucleotide is free from association with liposomal formulations, charged lipids, transfection-facilitating precipitating agents, and transfection-facilitating viral particles; wherein a sufficient amount of said composition is administered to allow incorporation of said polynucleotide into heart cells of said vertebrate; and wherein said polypeptide is expressed in the heart of said vertebrate. '694 suggested delivering interferons using DNA and delivering DNA to treat cancer. '694 did not teach IFN- α or obtaining expression levels of a protein in the serum that were capable of treating cancer by administering the DNA intramuscularly or into the peritoneal cavity as currently claimed. It is not readily apparent that administering polynucleotides to the heart as in '694 can be used to treat cancer or metastasis as claimed in the instant application.

US Application number 10/028,782 has been considered for potential double patenting; however, '782 is limited to administering RNA which is patentably distinct from administering a DNA plasmid as claimed in the instant invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

Art Unit: 1632

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on 571-272-0735.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

A handwritten signature in black ink, appearing to read 'mi' followed by a series of loops and a long horizontal stroke.

**MICHAEL WILSON
PRIMARY EXAMINER**